

REMARKS

Claims 3, 6, 26, 28-36, and 41-42 have been amended and no new claims have been added. Support for these amendments can be found throughout the claims and specification as filed. Specifically, support may be found in the specification at page 47, lines 23-26; at page 48, lines 1-5; at page 65, line 22; and at page 81, line 16. No new matter has been added by way of amendment. Accordingly, claims 1-3, 6, and 25-42 will be pending upon entry of this amendment.

The Rejection of Claims 26, 30 and 35 Under 35 USC §112, Second Paragraph

Should Be Withdrawn

Claims 26, 30 and 35 were rejected by the Examiner under 35 USC §112, Second Paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicant regards as the invention. The Examiner rejected claim 26, which recites, "The isolated nucleic acid of claim wherein the nucleic acid..." and noted that the claim does not refer to any specific claim. The Examiner also rejected claims 30 and 35 for being dependent claims.

Applicants have amended claim 26 to correct the prior inadvertent typographical error, to recite, "The nucleic acid of claim 1 wherein the nucleic acid..." Applicants respectfully request reconsideration and withdrawal of the rejection of claims 26, 30 and 35 under 35 USC §112, Second Paragraph.

The Rejection of Claims 1, 3, 6, 26-28, 30, 31, 33, 35, 36, and 40-42 Under 35 USC §112,

First Paragraph (Enablement) Should Be Withdrawn

Claims 1, 3, 6, 26-28, 30, 31, 33, 35, 36, and 40-42 were rejected by the Examiner under 35 USC §112, First Paragraph as failing to comply with the enablement requirement. The Examiner argued that "the specification, while being enabling for:

An isolated 47324 nucleic acid molecule selected from a) a nucleic acid molecule comprising the nucleotide sequence of SEQ ID NO:1; and b) a nucleic acid molecule comprising the nucleotide sequence of SEQ ID NO:3, as well as a vector comprising said isolated nucleotide sequence(s) and an isolated host cell comprising said isolated nucleotide sequence;

does not reasonably provide enablement for the full scope of the instant claims.

Specifically, the instant claims are not enabled for any nucleotide sequence encoding the amino acid sequence of SEQ ID NO:2, a host cell comprising any nucleotide sequence encoding the amino acid sequence of SEQ ID NO:2, a method of producing said amino acid sequence, and a non-isolated host cell comprising said isolated nucleic acid sequence."

The Examiner argued that the specification is not enabling for any nucleic acid encoding SEQ ID NO:2, stating that undue experimentation would be required in order to practice the invention as claimed. Applicants respectfully traverse the rejection and submit that in fact the specification is enabling for any nucleic acid encoding SEQ ID NO:2. First, Applicants submit that there is considerable direction and guidance in the specification, as the **exact** amino acid sequence to be encoded by the claimed nucleotide sequences of the claimed invention is set forth in SEQ ID NO:2. Second, Applicants submit that the requisite knowledge to determine the number and nucleotide sequence of any possible nucleic acid molecule encoding the polypeptide set forth in SEQ ID NO:2, including the Genetic Code and “wobble hypothesis,” existed as well-known among those in the relevant art at the time of filing (see, for example, pages 230-232 of Alberts et al. submitted herewith as IDS Citation No. CA). Applicants further submit that the number of nucleotide sequences encoding SEQ ID NO:2 is *finite and not unlimited*. Starting with the amino acid sequence of SEQ ID NO:2, one of skill in the art could use this information to precisely determine the exact nucleotide sequence of any and every nucleic acid encoding SEQ ID NO:2. Thus, one of ordinary skill in the art, given the sequences set forth in the instant sequence listing, the teachings provided in the specification, and information well-known in the art at or before the time of filing, would very predictably be able to practice the claimed invention without undue experimentation.

In consideration of the factors to be assessed for determination if the amount of experimentation required to carry out an invention is undue, and as such not fully enabled, Applicants submit review of the factors supports a determination of the present disclosure as being fully enabled.

For instance, as acknowledged by the Examiner, the nature of the invention relates to biotechnology and the level of skill in the art is high. As discussed above, the predictability of the sequences’ ability to code for the amino acid sequence of SEQ ID NO:2 is very predictable (*i.e.* completely predictable as each permutation can be readily determined). The breadth of the claims, though broad, is entirely finite and limited due to the single amino acid sequence encoded. Furthermore, as discussed, the specification provides the defined sequence SEQ ID NO:2, as well as exemplary encoding sequences. In combination with the specification and knowledge in the art, the guidance provided is high. Finally, while experimentation would be necessary to generate sequences encoding SEQ ID NO:2, such experimentation is well within the skill in the art and is in no way undue. Applicants thus submit that the specification is in fact enabling for nucleic acid molecules encoding SEQ ID NO:2, and respectfully request reconsideration and withdrawal of the rejection.

The Examiner has seemingly focused his argument around the premise that “there is no disclosure provided which indicates that the protein levels (of SEQ ID NO:2) are commensurate with the corresponding mRNA levels, which would be required in order for the protein levels to be diagnostic indicators of cancer, etc.” The Examiner pointed to Meric *et al.*, Gokman-Polar, and Goetzl *et al.* as

examples of instances where the authors found that mRNA levels are not always indicative of the corresponding protein level for the molecules studied. Applicants respectfully traverse the rejection and submit that the claims, drawn to nucleic acid molecules, vectors, host cells, and a method for producing a polypeptide utilizing said nucleic acid molecules, do not require knowledge of any definitive necessary correlation between mRNA and protein levels. Even assuming *arguendo* that the Examiner's arguments are true in some in vivo situations, such assessment is not relevant to the presently claimed subject matter relating to isolated nucleic acids, host cells, and methods of producing polypeptides. For the reasons discussed above, the presently claimed subject matter is fully enabled.

The Examiner also pointed out that the claims encompass a non-isolated host cell. The Examiner cited a number of references regarding the generation of transgenic animals, and stated "Furthermore, considering that the claims encompass cells in transgenic animals (*i.e.* non-isolated cells comprising the isolated nucleic acids), additional experimentation would be required to overcome the problems recognized in the art." Without acquiescing to the Examiner's arguments, Applicants respectfully submit that transgenic animals are not intended to be encompassed within claims directed to host cells. Applicants have amended claims 3 and 32-36 to replace the phrase "A host cell" with the phrase "An isolated host cell." Applicants submit that these amendments render the rejection of claims based on non-isolated host cells moot.

In view of the remarks and amendments above, Applicants submit that the specification as filed is enabling for the full scope of the claimed invention. Therefore, Applicants respectfully request reconsideration and withdrawal of the rejection of claims 1, 3, 6, 26-28, 30, 31, 33, 35, 36, and 40-42 under 35 USC §112, First Paragraph (enablement).

Claim Objections

The Examiner objected to claims 2 and 25 as being dependent upon a rejected base claim (claim 1). In view of the foregoing remarks and amendments, Applicants submit that the base claim is proper, and respectfully request reconsideration and withdrawal of the objection.

The Examiner also objected to claims 21-31 because of the following informalities: "the claims start with the article 'An'..." The Examiner suggested "the claims be amended to start with the article 'The' in order to clearly set forth the claims..." Applicants respectfully submit that the reference from which each claim depends is clearly set forth and is not improper. However, in an effort to advance prosecution and to address the Examiner's concern, Applicants have amended claims 28-31 to replace the article "An" with the article "The". Applicants submit that claims 21-24 were canceled in a previous amendment, claims 25 and 26 currently start with the article "The", and claim 27 is an independent claim and therefore properly starts with the article "An". Applicants therefore respectfully request reconsideration and withdrawal of the objection to claims 21-31.

CONCLUSIONS

In view of the amendments and remarks herein, Applicants respectfully submit that the objections and rejections presented by the Examiner are now overcome and that this application is in condition for allowance. If, in the opinion of the Examiner, a telephone conference would expedite the prosecution of the subject application, the Examiner is invited to call the undersigned.

This paper is being filed timely as it is being sent within the three month period for response. In the event any extension of time is necessary, the undersigned hereby authorizes the requisite fees to be charged to Deposit Account No. 501668.

Entry of the remarks made herein is respectfully requested.

Respectfully submitted,

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